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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,925	03/10/2004	Wumin Li	AM 101333	3270

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EXAMINER	
TONGUE, LAKIA J	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,925	LI ET AL.	
	Examiner	Art Unit	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 9, 2007 has been entered.

Claim 22 is currently amended. Claims 22-24 are pending and under examination.

Declaration

1. The declaration by Wumin Li filed July 9, 2007 has been considered.

Rejections Maintained

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The rejection of claims 22, 23 and newly added claim 24 under 35 U.S.C. 103(a) as being unpatentable over Doyle et al (U.S. Patent 5,965,128), in view of Clancy et al. (U.S. 2004/0057965 A1), and further in view of the SIGMA Catalog (Biochemicals and

Reagents for life science, 2000-2001, Adjuvants, pages 1472) is maintained for the reasons set forth in the previous Office action.

Applicant argues that:

1) There is no motivation or desirability in the art itself to combine or modify the references and arrive at the claimed invention.

2) Examining exactly what the collective art fairly teaches to the ordinary practitioner, it is clear that the practitioner could not determine the instant claim limitations without inventive effort.

3) The practitioner would be discouraged from finding an injectable formulation for reducing shedding of *E. coli* O157:H7 in cattle.

4) The declaration statements of inventor, Dr. Wumin Li provide a side-by-side comparison of the novel formulation of the present invention with a typical veterinary vaccine formulation commonly used for bacterial antigens. Moreover, the showing of better benefits and practical advantages of the unique metabolizable oil adjuvant in Applicants' vaccine composition is surprising in view of the state of the art.

5) Clancy et al. do not describe, exemplify or suggest any antigens that colonize the intestinal tract let alone *E. coli* O157:H7.

6) A generic list of adjuvants from one chemical supplier's catalog does not provide any teaching of which particular adjuvant can be used in concert with which antigen for what results.

Applicant's arguments have been fully considered and deemed non-persuasive.

The instant invention is drawn to a method for reducing shedding of *E. coli* O157:H7 in an animal which comprises administering by injection to the animal an effective amount of a vaccine composition containing *E. coli* O157:H7, wherein the vaccine composition comprises inactivated or killed whole *E. coli* O157:H7, a metabolizable oil adjuvant and optionally a pharmaceutically acceptable carrier. Subsequent claim 24 recite wherein the method produces minimal injection site reaction.

With regard to Points 1 and 2, in response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

However, KSR forecloses the argument that a **specific** teaching, suggestion, or motivation is required to support a finding of obvious. See the recent Board decidion *Ex parte Smith,--USPQ2d--*, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR, 82 USPQ2d* at 1396). In this instance all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would

have yielded predictable results to one of ordinary skill in the art at the time of the invention.

With regard to Point 3, contrary to Applicant's argument, Doyle et al. disclose that the bacteria can be formulated as an inoculant paste to be directly injected into an animal's mouth (see column 5, lines 29-30). Thus meeting the limitation of administering by injection and further meeting the limitation of producing minimal injection site reaction.

With regard to Point 4, the declaration under 37 CFR 1.132 filed July 9, 2007 is insufficient to overcome the rejection of claims 22, 23, and newly added claim 24 because the facts presented are not commensurate in scope with the claims.

Specifically, the instant claims are drawn to a metabolizable oil adjuvant, which is not commensurate in scope with the declaration, which discloses that the metabolizable oil adjuvant of the present invention comprises aluminum hydroxide and SP Oil. The term "SP Oil" designates an oil emulsion comprising a polyoxyethylene-polyoxypropylene block copolymer, squalene, polyoxyethylene sorbitan monooleate (Tween 80, an emulsifier) and a buffered salt solution. The declaration is silent with regard to which metabolizable oil adjuvant is used as the declaration discloses a combination of "SP Oil" which includes a metabolizable oil adjuvant (i.e. squalene).

Additionally, the district court held that in *Bristol-Meyers Squibb. Abbott,* No. 01-CV-1867, slip op. at 42-43 (citing 246 F.3d at 1376) an inventor may not obtain a patent on a process having the same steps as a prior art process, in which the new process merely identifies a new, advantageous property of the prior art process. In the instant

case Applicant argues that adding a metabolizable oil adjuvant to an effective amount of a vaccine composition containing *E. coil* O157:H7 will reduce shedding of *E. coil* O157:H7 in an animal as well as produce minimal injection site reaction, which is intended to be the new, advantageous property.

With regard to Point 5, Clancy et al. does not just describe respiratory tract vaccines. Clancy et al. disclose compositions and vaccines, which can be applied to any potential mucosal pathogen and any mucosal surface, including the intestinal tract. Further, Clancy et al. supports administering whole inactivated bacteria together with an adjuvant for the treatment of an intestinal infection (see paragraphs 0005, 0006, and 0010). Finally, Doyle et al. specifically disclose their method reduces "carriage and fecal shedding of *E. coli* O157: H7" (see column 2, lines 65-67).

With regard to Point 6, Clancy et al. teach that known conventional and suitable pharmaceutical adjuvants should be included when preparing suitable formulations and would be well known to those skilled in the art. The Sigma catalog teaches a list of known conventional and suitable pharmaceutical adjuvants. As Clancy et al. disclose that any known conventional adjuvant can be used, it would have been obvious to the skilled artisan to use any known adjuvant and that they would necessarily expect the same outcome

As previously presented, Doyle et al. teach a method for reducing shedding of *E. coli* O157:H7 in an animal by administering an effective amount of *E. coli* O157:H7 to infected animals (column 5, lines 58-61). Moreover, Doyle et al. teach the administration of a strain or combination of probiotic bacteria (column 2, lines 61-67).

Doyle et al. does not teach a vaccine specifically comprising inactivated or killed whole *E. coli* O157:H7, a metabolizable oil adjuvant or an effective amount of *Lactobacillus acidophilus*. Lastly, Doyle et al. teach the bacteria can be formulated as an inoculant paste to be directly injected into an animal's mouth (see column 5, lines 29-30). Thus meeting the limitation of administering by injection and further meeting the limitation of producing minimal injection site reaction.

Clancy et al. teaches a method for the treatment of mucosal infections which comprises administering compositions to any potential surface pathogen (i.e. the intestinal tract; see paragraphs 0015, 0017). Clancy et al. teaches that the mucosally administrable compositions comprises one or more antigens derived from at least one microorganism which is capable of causing infection at a mucosal surface and a probiotic. The microorganism is a whole killed, live or live attenuated microorganism (see paragraphs 0005-6). Clancy et al. teaches that an affective amount is from about $1x10^{8}$ to about $1x10^{12}$ (see paragraph 0025). Moreover, the composition may be combined with known pharmaceutically acceptable carriers, solvents and excipients (see paragraph 0008). A preferred probiotic to be used in the composition is *Lactobacillus acidophilus* among others (see paragraph 0009). Lastly, Clancy et al. teaches that a range of suitable pharmaceutical adjuvants can be used and would be well known to those skilled in the field of pharmaceutical formulations. Clancy et al. does not specifically teach a metabolizable oil adjuvant.

The Sigma catalog teaches commonly used adjuvants, which include but are not limited to squalene, which is a metabolizable oil (see paragraph 1472).

Doyle et al. and Clancy et al. teach analogous inventions related to methods for treating infections of the intestinal tract by administering a composition, which comprises an antigen, a probiotic and optionally a pharmaceutical carrier. It would have been *prima facie* obvious to a person having ordinary skill in the art at the time the invention was made to modify the invention of Doyle et al. with the teaching of Clancy et al. because Clancy et al. teaches combining whole killed microorganism together with an adjuvant and a probiotic. Moreover, it would be obvious to modify the invention of Doyle et al. and Clancy et al. with the Sigma catalog because the Sigma catalog teaches commonly used commercial adjuvants that are used to enhance an immune response. It would have been expected, barring evidence to the contrary, that the method would be effective in reducing the shedding of *E. coli* O157:H7.

3. The rejection of claims 22, 23 and newly added claim 24 under 35 U.S.C. 103(a) as being unpatentable over Doyle et al. (U.S. Patent 5,965,128), in view of Clancy et al. (U.S. 2004/0057965 A1), and further in view of the SIGMA Catalog (Biochemicals and Reagents for life science, 2000-2001, Adjuvants, 1472) as applied to claims 22 and 23 above, and further in view of Molly et al. (U.S. 2005/0084500 A1) is maintained for the reasons set forth in the previous Office action.

Applicant argues that:

1) The earlier rejection of record further applying the cited reference of Molly et al. did not include claim 22.

2) Molly et al. merely suggest that neomycin be used in combination with the fungus to improve the gastrointestinal microbial ecosystem by suppressing pathogens on the gastrointestinal tract of the animals.

3) There are no specific formulations or examples that contain neomycin.

4) It is plain to see that Molly et al. do not promote the use of an animal feed antibiotic such as neomycin in the absence of fungus as it will have an adverse effect on the animal.

Claims 22, 23 and newly added claim 24 are drawn to a method for reducing shedding of *E. coli* O157:H7 in an animal which comprises administering by injection to the animal an effective amount of a vaccine composition containing *E. coli* O157:H7, wherein the vaccine composition comprises inactivated or killed whole *E. coli* O157:H7, a metabolizable oil adjuvant, optionally a pharmaceutically acceptable carrier and further comprising a neomycin medicated feed supplement to animals.

With regard to Point 1, claim 22 was inadvertently omitted from the preamble of the earlier rejection dated July 3, 2006. However, as all the limitations of said claim was addressed in the body of the rejection and fully incorporates the rejection which recited the rejection of claims 22 and 23 over Doyle et al. (U.S. Patent 5,965,128), in view of Clancy et al. (U.S. 2004/0057965 A1), and further in view of the SIGMA Catalog (Biochemicals and Reagents for life science, 2000-2001, Adjuvants, 1472), the rejection is deemed to be proper. The Examiner regrets the oversight and any inconvenience this may have caused.

With regard to Points 2 and 3, the instant claim recites open claim language and thus does not exclude other materials (i.e. fungus) from being present in the claimed composition. Moreover, the fact that there are no specific formulations or examples that contain neomycin alone is irrelevant. Lastly, it would be obvious to utilize the neomycin and the fungus because said fungus is edible and serves as an added supplement to the medicated feed.

With regard to Point 4, Applicant is reminded that the rejection is an obviousness rejection over the combination of said references. Further, contrary to Applicant's argument, Molly et al. teach a method of administering a composition, which comprises an animal feed antibiotic (neomycin) for the improvement of intestinal function against enteric pathogens and would be suitable for the suppression of enteric pathogens like *E. coli* (see paragraph 0059).

As previously presented the teachings of Doyle et al., in view of Clancy et al., and further in view of SIGMA have been taught above. Neither of them teaches administering a neomycin medicated feed supplement to an animal.

Molly et al. teaches a method for improving the gastrointestinal tract by enumerating enteric pathogens such as *Escherichia* (0059). The method is accomplished by administering useful compositions, which comprises an animal feed antibiotic including but not limited to neomycin (0036). Moreover, Molly et al. teaches that the composition can be suitable for the improvement of intestinal function and when fed to dairy animals such as cows, goats and ewes can improve milk production (0047).

In view of all of the above, it would have been *prima facie* obvious to a person having ordinary skill in the art at the time the invention was made to modify the invention of Doyle et al. with the teachings of Clancy et al. and with the teachings of the Sigma catalog with the teachings of Molly et al. because the composition of Molly et al. helps with the improvement of nutrient replenishment digestion and absorption as well as disease prevention. It would have been expected, barring evidence to the contrary, that the method would be effective in reducing the shedding of *E. coli* O157:H7.

4. The rejection of claim 22 under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (Effect of dairy calves with an inactivated *E. coli* O157:H7 bacterin on shedding of *E. coli* O157:H7, 1999; Abstract 40 aP), in view of SIGMA (Biochemicals and Reagents for life science, 2000-2001, Adjuvants, 1472) is maintained for the reasons set forth in the previous Office action.

Applicant argues that:

1) The teaching or suggestion to make the claimed composition comprising, at the very least, inactivated or killed whole *E. coli* O157:H7 and a metabolizable oil adjuvant must both be found in the prior art, not Applicant's disclosure.

2) Johnson et al. disclose a totally different vaccine composition containing inactivated *E. coli* O157:H7, inactivated verotoxin 2 and intimin O157, which does not suggest Applicants' efficacious vaccine formulation.

3) Neither Johnson et al. nor the Sigma Catalog describe or suggest the selection of the specific metabolizable oil adjuvant of the claimed method for the use with *E. coli* O157:H7.

4) The declaration demonstrates that the formulation of the present invention elicits a strong immune response yet surprisingly provides a minimal injection site reaction that avoids the anticipated adverse impact on meat quality.

Claim 22 is drawn to a method for reducing shedding of *E. coli* O157:H7 in an animal which comprises administering by injection to the animal an effective amount of a vaccine composition containing *E. coli* O157:H7, wherein the vaccine composition comprises inactivated or killed whole *E. coli* O157:H7, a metabolizable oil adjuvant and optionally a pharmaceutically acceptable carrier.

With regard to Point 1, in response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

However, KSR forecloses the argument that a **specific** teaching, suggestion, or motivation is required to support a finding of obvious. See the recent Board decidion *Ex parte Smith,--USPQ2d--*, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR, 82 USPQ2d* at 1396). In this instance all the claimed elements were known in the

prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

With regard to Point 2, the instant claim recite open claim language and thus does not exclude other materials (i.e. inactivated verotoxin 2 and intimin O157) from being present in the claimed composition. Moreover, Johnson et al. teach that shedding of the organism by most calves in each group fell to <50 CFU/g of feces within 2-3 weeks of challenge, thus meeting the limitation of reducing shedding of *E. coli* O157:H7 in an animal and meeting the requirement of a reasonable expectation of success.

With regard to Point 3, the claims are not drawn to a specific oil. The Sigma catalog, which was use to teach the use of a metabolizable oil adjuvant. The use of adjuvants is well known in the state of the art. Since the Sigma Catalog teaches a list of known conventional and suitable pharmaceutical adjuvants. it would have been obvious to use a metabolizable oil adjuvant from the Sigma catalog.

With regard to Point 4, the declaration under 37 CFR 1.132 filed July 9, 2007 is insufficient to overcome the rejection of claim 22 based upon the basis for all obviousness rejections, which states that a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject

matter pertains. Patentability shall not be negatived by the manner in which the invention was made as set forth in the last Office action because: the facts presented are not germane to the rejection and are not commensurate in scope with the claims.

Moreover, the instant claims are drawn to a metabolizable oil adjuvant, which is not commensurate in scope with the declaration, which discloses that the metabolizable oil adjuvant of the present invention comprises aluminum hydroxide and SP Oil. The term "SP Oil" designates an oil emulsion comprising a polyoxyethylene-polyoxypropylene block copolymer, squalene, polyoxyethylene sorbitan monooleate (Tween 80, an emulsifier) and a buffered salt solution. The declaration is silent with regard to which metabolizable oil adjuvant is used as the declaration discloses a combination of "SP Oil" which includes a metabolizable oil adjuvant (i.e. squalene).

Additionally, the district court held that in *Bristol-Meyers Squibb. Abbott,* No. 01-CV-1867, slip op. at 42-43 (citing 246 F.3d at 1376) an inventor may not obtain a patent on a process having the same steps as a prior art process, in which the new process merely identifies a new, advantageous property of the prior art process.

As previously presented, Johnson et al teaches a method of vaccination calves with 10^{10} CFU of inactivated *E. coli* O157:H7 bacterin to reduce the shedding of the organism. Johnson et al does not teach a metabolizable oil adjuvant or the optional pharmaceutically acceptable carrier.

The Sigma catalog teaches commonly used adjuvants include but are limited to squalene, which is a metabolizable oil (1472).

It would have been *prima facie* obvious to a person having ordinary skill in the art at the time the invention was made to modify the invention of Johnson et al with the teaching the Sigma catalog because it is obvious to add an adjuvant to vaccine because they are used to enhance an immune response and the Sigma catalog teaches commonly used commercial adjuvants. It would have been expected, barring evidence to the contrary, that the method would be effective in reducing the shedding of *E. coli* O157:H7. Limitations such as "optionally" are being viewed as a limitations that may or may not be present in the prior art.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejected claims are drawn to a method for reducing shedding of *E. coli* O157:H7 in an animal which comprises administering by injection to the animal an effective amount of a vaccine composition containing *E. coli* O157:H7, wherein the

vaccine composition comprises inactivated or killed whole *E. coli* O157:H7, a metabolizable oil adjuvant and optionally a pharmaceutically acceptable carrier.

To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus of a metabolizable oil adjuvant or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession of the claimed invention. In the instant case, to fulfill the written description requirement, a representative number of metabolizable oil adjuvants that are capable of reducing or producing minimal injection site reaction. Specifically, the specification needs to provide guidance as to which metabolizable oil adjuvants can be used to aid in reducing the shedding of *E. coli* O157:H7 in an animal as well as produce minimal injection site reaction.

A representative number of species means that the species that are adequately described are representative of the entire genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such

identifying characteristics, sufficient to show the Applicant was in possession of the claimed genus.

Moreover, the skilled artisan cannot envision the detailed chemical structure of the claimed gene(s). The claims encompass a genus of metabolizable oil adjuvants, which are not adequately described. The specification fails to provide any additional representative species of the claimed genus to show that Applicant was in possession of the claimed genus.

The specification is silent with regard to which metabolizable oil adjuvant can be used in combination with the claimed immunogen to reduce shedding as well as produce minimal injection site reaction. The specification discusses that when a suitable adjuvant (e.g. metabolizable oil) is used in combination with *E. coli* O157:H7 the composition is safened for use and provides effective immunization and safety with minimal injection site reactions (see page 4, lines 3-7). However, the specification generically discloses that the present invention contains a suitable adjuvant which more specifically contains a metabolizable oil adjuvant as one of its components (see page 5, lines 13-15). The claims are broadly drawn to any metabolizable oil adjuvant, however the specification only specifically discloses the use of an adjuvant referred to as "SP OIL", which contains oil emulsion comprising a polyoxyethylene-polyoxypropylene block copolymer, squalane, polyoxyethylene sorbitan monooleate and a buffered salt solution. The specification further discloses that in a highly preferred vaccine composition of the present invention, the metabolizable oil is utilized in conjunction with aluminum hydroxide gel, preferably in an amount of about 10-20% vol/vol, and most preferably in

an amount of about 15% vol/vol. Moreover, this combination of SP oil and aluminum hydroxide provides an especially useful vaccine in that both systemic and local immune effects are induced in the vaccinated ruminant. The specification is silent with regard to which metabolizable oil adjuvant alone accomplishes the goal of the instant claims (see page 6, lines 3-21).

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential ability to bind a specific biological agent. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

The University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404. 1405 held that: ...To fulfill the written description requirement, a patent specification must describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an Applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention."

Lockwood, 107 F.3d at 1572, 41 USPQ2datl966.

Conclusion

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
8/31/07

ROBERT A. ZEMAN
PRIMARY EXAMINER